DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

D1136B

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

January 28, 1997

cc: HFI-35/FOI Staff
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 97-30

Donald L. Hillestad
President
Hillestad International, Inc.
178 Hwy. 51 North
Woodruff, Wisconsin 54568

Dear Mr. Hillestad:

This letter is written in reference to the marketing of the products Z-23 Prostate Formula, Opti-Cran Freeze-dried Cranberry with Aloe, Citri-C Wafers, Ginseng Plus "C" Chewing Gum and Dialyvite Multi-vitamins for Chronic Renal Failure by your firm.

Product labeling, namely immediate container labels, product brochures, the newsletter "Quality Living," and the catalog "Quality Family Products," suggests that the products Z-23 Prostate Formula, Opti-Cran Freeze-dried Cranberry with Aloe and Dialyvite Multi-vitamins for Chronic Renal Failure are useful for treating or preventing various disease conditions. Product labeling for the products Citri-C Wafers and Ginseng Plus "C" Chewing Gum suggest that these products are useful as smoking deterrents. Details of these statements are further discussed below. The claims made for these five products cause each to be drugs [Section 201(g) of the Federal Food, Drug and Cosmetic Act (the Act)].

1. Z-23 Prostate Formula
   The product brochure claims that this product may be useful in the treatment or prevention of prostate cancer and benign prostatic hypertrophy. The front page of the November 1995 edition of the newsletter "Quality Living" claims that this product may be useful in treating or preventing "Prostate problems."

2. Dialyvite Multi-vitamins for Chronic Renal Failure
   The immediate container label for this product claims that this product is useful in the treatment or prevention of chronic renal failure.

3. Opti-Cran Freeze-dried Cranberry with Aloe
   The product brochure claims that this product is useful in the treatment or prevention of bladder and urinary tract infections and that components of the product act as infection fighters and have anti-inflammatory and anti-bacterial properties.

4. Citri-C Wafers and Ginseng Plus "C" Chewing Gum
   The immediate container labels for these two products bear the statements "Replace smoking urges with a Citri-C chewable wafer" and "Replace smoking urges with Ginseng Plus 'C' Chewing Gum," respectively. Further, the "Quality Family Products" catalog, in the section concerning Citri-C Wafers, states that this product may be used "as an aid in quitting smoking."

   Under Title 21 of the Code of Federal Regulations Part 310.544 (copy enclosed), smoking-deterrent drug products may not be marketed except under an approved new drug application (NDA).

We are unaware of any evidence that the aforementioned five drug products are generally recognized as safe and effective for their intended uses. Therefore, these drugs are new drugs (Section 201(p)] which may not be marketed in this country since no New Drug Applications (Section 505) have been approved for these drugs. These drugs are misbranded in that their labeling is false and misleading because it suggests that the drugs are generally regarded as safe and effective for

their intended uses when, in fact, this is not the case. The drugs are further misbranded because their labeling fails to bear adequate directions for use (Section 502).

This letter does not represent a comprehensive review of all the products distributed by your firm, nor does it represent a complete review of all product labeling including immediate container labels, product brochures, product catalogs and newsletters. As the president of your firm, it is your responsibility to ensure that all products distributed by your firm meet the requirements of the Act and the regulations promulgated thereunder.

We request that you notify this office in writing within 15 working days of receipt of this letter stating the action you will take to discontinue the marketing of these drugs or otherwise bring them into compliance. Failure to promptly correct these violations may result in enforcement action being initiated without further notice. The Act provides for seizure of illegal products (Section 303) and for injunction (Section 302) against the manufacturer and/or distributor of illegal products.

Your reply should be directed to Compliance Officer Howard E. Manresa at the address indicated on the letterhead. Mr. Manresa may be reached at (612) 334-4100 ext. 156.

Sincerely yours,

John Feldman
Director
Minneapolis District

JFH HEM/ccl

Enclosure: 21 CFR 310.544